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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460



United States
Environmental Protection
Agency

Office of Pesticide Programs

Antimicrobials Division (AD)

March 26, 2014.

MEMORANDUM

Subject: Product Chemistry Review for EPA Reg # 89896-E.
Product Name: **CleanSmart**
DP #: 417077

From: Salvador Rodriguez, Chemist
Product Science Branch, CT Team
Antimicrobials Division (7510P)

Thru: Karen P. Hicks, CT Team Leader
Product Science Branch
Antimicrobials Division (7510P)

To: Demson Fuller.
PM Team 32

APPLICANT: Simple Science, LLC

Action code: A540

Due date: 05/19/14

Product Formulation from label
Active Ingredient(s)

% by wt.

Hypochlorous acid 0.017

BACKGROUND:

The registrant, Simple Science, LLC, has submitted the OPPTS Guideline, Series 830 Tables "A & B" to support the new registration for the disinfectant, integrated, non-food, end-use product, **CleanSmart**. The Product Chemistry Reviewer has reviewed the following documents:

- Confidential Statement of Formula (CSF), dated 11/26/13 for the basic and formulation.
- Cover & transmittal letter, dated 11/26/13. MRID #: 49260300
- Data matrix, dated 11/26/13.
- Label, dated 11/26/13.
- OPPTS Guideline, Series 830, Tables "A & B". Study titled: "Group A & B Product Chemistry for CleanSmart" MRID #s: 49260301, 49260302, 49260303 & 49260304.

FINDINGS:

1. The CSF, dated 11/26/13, for the basic formulation is revised.
2. All the certified limits meet the EPA 40 CFR standard certified limits. The registrant has provided a justification letter, dated 11/18/13, for the use of wider certified limits for the active ingredient (AI).
3. The CSFs and the label have the same nominal.
4. The OPPTS Guidelines Group "A & B" product chemistry data requirements applicable to end-use products have been met. MRID #s: 49260301, 49260302, 49260303, & 49260304.
5. The registrant indicated that five pilot-scale batches for the product **CleanSmart** were selected for performing the Preliminary Analysis Study. Using the Enforcement Analytical Method, samples were analyzed and the mean of the five readings was used to express the weight % active ingredient (AI) in each sample.

The results are the following:

Lot #	%purity of Silver Nitrate
001	0.0166
002	0.0170
003	0.0168
004	0.0169
005	0.0169

6. The results of the accelerated (14 days) storage and of the test material have been determined. The study is in accordance with the requirements of the US EPA, Office of Prevention, Pesticides and Toxic Substances, Series 830: Products Properties Test Guidelines OPPTS 830.6317 & 830.6320.
7. After 14 days, no pitting, no thinning, no warping, no change in color, no cracks holes or mottling were noted for the commercial packaging material. Upon mechanical deformation, neither the container nor the closure cracked or split. In conclusion there was no significant change in the active ingredient content of the test material during the two years of storage.

Timepoint	Replicate 1	Replicate 2	Replicate 3
After 14 days at 54° C	0.017	0.0171	0.0170

CONCLUSIONS:

Product Science Branch of Antimicrobials Division finds the OPPTS Guideline, Series 830 group "A" and "B" product chemistry requirements for the integrated, non-food use, end-use products **CleanSmart** to be acceptable. The results of the five batch analysis and from the Storage Stability & Corrosion Characteristics essays are within the EPA standard certified limits.

PRODUCT CHEMISTRY REVIEW

I. CONFIDENTIAL STATEMENT OF FORMULA

a. Type of formulation and source registration:

- Non-integrated formulation system []
- Are all TGAs used registered? Yes [] No []
- Integrated formulation system [X]
- If "ME-TOO," specify EPA Reg. No. of existing product: 87518-1

b. Clearance of inerts for non-food or food use:

The product is cleared for food use under 40 CFR §§180.940 and 180.950.
Yes [] No [X]

c. Physical state of product:

Liquid.

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

Yes [X] No []

f. Active ingredient

	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
Hypochlorous acid	0.017	0.010	0.017

g. For products produced by an integrated formulation system:

- Do all impurities of toxicological significance have a UCL?
Yes [X] No [] Not applicable [X]
- Have all impurities of $\geq 0.1\%$ in the product been identified?
Yes [] No [] Not applicable [X]

II PRODUCT LABEL

a. The active ingredient statement (chemical IDs and NC) is consistent with the CONFIDENTIAL STATEMENT OF FORMULA. Yes ☒ No ☐

b. The formula contains one of the following:

- | | | |
|--|------------------------------|--|
| • 10% or more of a petroleum distillate: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • 1.0% or more of methyl alcohol: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • sodium nitrite at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • a toxic List 1 inert at any level: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| • arsenic in any form: | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

c. If "yes" to any of the above, does the inert ingredients statement contain a footnote indicating this? Yes ☐ No ☐ Not applicable ☒

d. Appropriate warning statement(s) regarding flammability or explosive characteristics of the product are listed on the label.

Yes ☐ No ☐ Not applicable ☒

e. The storage and disposal instructions for the pesticide container are in compliance with PR Notice 84-1 for household use products or PR Notice 83-3 for all other uses.

Yes ☒ No ☐

f. The product requires an expiration date at which time the NC falls below the LCL (based on the 1-year storage stability data or other information).

Yes ☐ No ☒

Table A:
Product Chemistry (Series 830, Group A)

Data Requirements	Acceptance of Information	MRID No.
830.1550 Product Identity ¹	A	49260301 49260302
830.1600 Description of Materials	A	49260301 49260302
830.1620 Production Process ²	N/R	
830.1650 Formulation Process ³	A	49260301 49260302
830.1670 Formation of Impurities ⁴	A	49260301 49260302
830.1700 Preliminary Analysis ⁵	A	49260302
830.1750 Certified Limits ⁶	A	49260301 49260302
830.1800 Enforcement Analytical Method ⁷	A	49260301 49260302
830.1900 Submittal of Samples	<i>[Samples are to be provided on a case-by-case basis for end-use products.]</i>	

Explanation: A=acceptable; N=not acceptable (i.e., item was submitted but is not acceptable); NA=technically not applicable (i.e., not required); G=data gap (i.e., item was not submitted but is required); U=requires upgrading (i.e., item is unacceptable but upgradeable); W=waived; E=EPA estimate.

¹See Confidential Appendix A for additional information.

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard CLs recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

Table B:
Physical and Chemical Characteristics (Series 830, Group B)

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.6302 Color	N/R		49260303
830.6303 Physical State	A	Liquid	49260301 49260303
830.6304 Odor	A	Chlorine odor.	49260301 49260303
830.6313 Stability to Normal and Elevated Temperatures, Metals, and Metal Ions	NR		
830.6314 Oxidation/Reduction; Chemical Incompatibility	A	EPA has found this product, to be neither an oxidizer nor a reducer.	49260303
830.6315 Flammability/Flame Extension	A	No flash; Sample boiled at ~98° C	49260303
830.6316 Explodability	A	Contains no volatile materials.	
830.6317 Storage Stability	A	Accelerated Storage Stability has been provided.	49260304
830.6319 Miscibility ¹	A	Completely inorganic – not soluble with any organic solvent.	49260301
830.6320 Corrosion Characteristics	A	The product & container are stable.	49260304
830.6321 Dielectric Breakdown Voltage	A	The product is not intended for use in or around electrical equipment.	
830.7000 pH ²	A	7 ± at 20° C	49260301 49260303
830.7050 UV/Visible Absorption	NR		
830.7100 Viscosity	N/R		
830.7200 Melting Point/Melting Range	N/R	The product is a liquid.	
830.7220 Boiling Point/Boiling Range	NR	100° C	49260302 49260303 49260304
830.7300 Density/Relative Density/Bulk Density	A	8.399 lbs/gal & 1.0012 g/cc	49260301 49260303
830.7370 Dissociation Constants in Water	N/R		

Physical/Chemical Properties*	Acceptance of Data	Value or Qualitative Description	MRID No.
830.7520 Particle size, fiber length, and diameter distribution.	N/R	.	
830.7840/830.7860 Water Solubility	NR		
830.7950 Vapor Pressure	NR		

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* Provide brief description, e.g., color – yellow or property value, e.g., density 1.25 g/cc. Unless otherwise indicated, the property should be at 25°C.

¹If product is an emulsifiable liquid

²If product is dispersible with water

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March 26, 2014.

EPA Reg#: 89896-E		DP Barcode: 417077	
		Submission #: 944308	
Product name: CleanSmart		Registrant: Simple Science, LLC	
Reviewer's name: Salvador Rodriguez		AD/PSB/CTT- Product Chemistry	
Agency due date: 05/19/14		PSB received date: 01/10/14	
CTT received date: 01/10/14		Science due date: 04/19/14	
Formulation type: EUP			
Integrated system: <input checked="" type="checkbox"/>		Non integrated system: <input type="checkbox"/>	Food use: <input type="checkbox"/> Non food use: <input checked="" type="checkbox"/>
Action Code: A540		Date Completed: March 26, 2014	
PC Code	CAS #	Active Ingredient Names	% wt (label)
129054	7790-92-3	Hypochlorous Acid	0.017
			
Test Lab: Simple Science Limited			
MRID(s): 49260301, 49260302, 49260303 & 49260304.			
Approver: Karen P. Hicks		Approved date: March 26, 2014.	
Guideline: OPPTS Guideline. Series 830 Groups "A & B"			
Comments:			


104/02/14

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b. Clearance of inerts for non-food or food use:

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Yes [] No [X]

c. Physical state of product:

Liquid.

d. The chemical IDs and analytical information (including that for the TGAs), density, pH, and flammability are consistent with that given in 830 Series, Group B.

Yes [X] No []

e. The NCs and CLs are acceptable.

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	<u>NC</u> (%)	<u>LCL</u> (%)	<u>UCL</u> (%)
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